Exhibit 2

FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated

Back to Cosmetics & U.S. Law (/cosmetics/laws-regulations/cosmetics-us-law)

Translations

- Español (/media/101035/download) (Spanish, PDF: 143KB)
- Français (/media/101041/download) (French, PDF: 126KB)
- 中文 (/media/101058/download) (Simplified Chinese: 157PDF KB)
- 中國 (/media/101066/download) (Traditional Chinese, PDF: 460KB)
- Português (/media/116738/download) (Portuguese, PDF: 118K)
- 한국어 (/media/101073/download) (Korean, PDF: 403KB)

The law does not require cosmetic products and ingredients, other than color additives, to have FDA approval before they go on the market, but there are laws and regulations that apply to cosmetics on the market in interstate commerce.

The two most important laws pertaining to cosmetics marketed in the United States are the Federal Food, Drug, and Cosmetic Act (/federal-food-drug-and-cosmetic-act-fdc-act) (FD&C Act) and the Fair Packaging and Labeling Act (FPLA) (https://wayback.archive-it.org/7993/20170722051950/https:/www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/ucm148722.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). FDA regulates cosmetics under the authority of these laws.

In the United States, federal laws are enacted by Congress. In order to make the laws work on a day-to-day level, Congress authorizes certain government agencies. such as FDA, to create regulations. A change in FDA's legal authority over cosmetics would require Congress to change the law.

- What kinds of products are "cosmetics" under the law?
- What does the law say about the safety and labeling of cosmetics?
- Does FDA approve cosmetics before they go on the market?
- Who is responsible for substantiating the safety of cosmetics?
- Can FDA order the recall of a hazardous cosmetic from the market?
- What actions can FDA take against companies or individuals who market adulterated cosmetics?

- Can FDA inspect cosmetics manufacturers?
- Does FDA test cosmetics or recommend testing labs?
- Do cosmetics companies need to register with FDA or get an FDA license to operate?

What kinds of products are "cosmetics" under the law?

The FD&C Act defines cosmetics by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" (FD&C Act, sec. 201(i)). Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance intended for use as a component of a cosmetic product. It does not include soap. (To learn what products are considered "soap" for regulatory purposes, see "Soap (/cosmetics/products/soap-faqs)."

But, if the product is intended for a therapeutic use, such as treating or preventing disease, or to affect the structure or function of the body, it's a drug (/drugs) (FD&C Act, 201(g)), or in some cases a medical device (/medical-devices) (FD&C Act, 201(h)), even if it affects the appearance. Other "personal care products" may be regulated as dietary supplements or as consumer products. To learn more, see "Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?) (/cosmetics/laws-regulations/it-cosmetic-drug-or-both-or-it-soap)" and "Cosmetics Q&A: Personal Care Products (/cosmetics/consumers/cosmetics-safety-qa-personal-care-products)."

The information presented here applies only to the regulation of products that are cosmetics as defined by the FD&C Act.

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What does the law say about the safety and labeling of cosmetics?

The FD&C Act prohibits the marketing of **adulterated** or **misbranded** cosmetics in interstate commerce.

"Adulteration" refers to violations involving product composition–whether they result from ingredients, contaminants, processing, packaging, or shipping and handling. Under the FD&C Act, a cosmetic is **adulterated** if--

- "it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under conditions of use as are customary and usual" (with an exception made for coal-tar hair dyes (/cosmetics/products/hair-dyes));
- "it consists in whole or in part of any filthy, putrid, or decomposed substance";
- "it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health";

- "its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health"; or
- except for coal-tar hair dyes, "it is, or it bears or contains, a color additive (http://www.fda.gov/ForIndustry/ColorAdditives/default.htm) which is unsafe within the meaning of section 721(a)" of the FD&C Act. (FD&C Act, sec. 601)

"Misbranding" refers to violations involving improperly labeled or deceptively packaged products. Under the FD&C Act, a cosmetic is **misbranded** if–

- "its labeling is false or misleading in any particular";
- its label does not include all required information. (An exemption may apply to cosmetics that are to be processed, labeled, or repacked at an establishment other than where they were originally processed or packed; see Title 21, Code of Federal Regulations, section 701.9 (https://www.ecfr.gov/current/title-21/section-701.9).)
- the required information is not adequately prominent and conspicuous;
- "its container is so made, formed, or filled as to be misleading";
- it is a color additive, other than a hair dye, that does not conform to applicable regulations issued under section 721 of the FD&C Act; and
- "its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970." (FD&C Act, sec. 602)

Under the FD&C Act, a product also may be misbranded due to failure to provide material facts. This means, for example, any directions for safe use and warning statements needed to ensure a product's safe use.

In addition, under the authority of the FPLA, FDA requires a list of ingredients for cosmetics marketed on a retail basis to consumers (Title 21, Code of Federal Regulations (CFR), section 701.3). Cosmetics that fail to comply with the FPLA are considered misbranded under the FD&C Act. (FPLA, section 1456) This requirement does not apply to cosmetics distributed solely for professional use, institutional use (such as in schools or the workplace), or as free samples or hotel amenities.

FDA can take action against cosmetics on the market that are in violation of these laws, as well as companies and individuals who market such products.

Does FDA approve cosmetics before they go on the market?

FDA's legal authority over cosmetics is different from our authority over other products we regulate, such as drugs, biologics, and medical devices. Under the law, cosmetic products and ingredients do not need FDA premarket approval, with the exception of color additives. However, FDA can pursue enforcement action against products on the market that are not in compliance with the law, or against firms or individuals who violate the law.

In general, except for color additives and those ingredients that are prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that–

- the ingredient and the finished cosmetic are safe under labeled or customary conditions of use,
- the product is properly labeled, and
- the use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

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Who is responsible for substantiating the safety of cosmetics?

Companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with FDA.

FDA has consistently advised manufacturers to use whatever testing is necessary to ensure the safety of their products and ingredients. Firms may substantiate safety in a number of ways. FDA has stated that "the safety of a product can be adequately substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information." (Federal Register, March 3, 1975, page 8916).

In addition, regulations prohibit or restrict the use of several ingredients (https://www.ecfr.gov/current/title-21/part-700/subpart-b) in cosmetic products and require warning statements (https://www.ecfr.gov/current/title-21/part-740) on the labels of certain types of cosmetics.

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Can FDA order the recall of a hazardous cosmetic from the market?

Recalls of cosmetics are voluntary actions taken by manufacturers or distributors to remove from the marketplace products that represent a hazard or gross deception, or that are somehow defective (21 CFR 7.40(a). FDA is not authorized to order recalls of cosmetics, but we do monitor companies that conduct a product recall and may request a product recall if the firm is not willing to remove dangerous products from the market without FDA's written request. To learn more, see “FDA Recall Policy for Cosmetics (/cosmetics/recalls-alerts/fda-recall-policy-cosmetics).”

What actions can FDA take against companies or individuals who market adulterated or misbranded cosmetics?

FDA may take regulatory action if we have reliable information indicating that a cosmetic is adulterated or misbranded. For example, FDA can pursue action through the Department of Justice (http://www.justice.gov) in the federal court system to remove adulterated and misbranded cosmetics from

the market. To prevent further shipment of an adulterated or misbranded product, FDA may request a federal district court to issue a restraining order against the manufacturer or distributor of the violative cosmetic. Cosmetics that are not in compliance with the law may be subject to seizure. “Seizure” means that the government takes possession of property from someone who has violated the law, or is suspected of doing so. FDA also may initiate criminal action against a person violating the law.

In addition, FDA works closely with U.S. Customs and Border Protection (http://www.cbp.gov) to monitor imports. Under section 801(a) of the FD&C Act, imported cosmetics are subject to review by FDA at the time of entry through U.S. Customs. Products that do not comply with FDA laws and regulations are subject to refusal of admission into the United States. They must be brought into compliance (if possible), destroyed, or re-exported. FDA does not inspect every shipment of cosmetics that comes into this country, but imported cosmetics are still subject to the laws we enforce, even if they are not inspected upon entry. To learn more, see “Information for Cosmetics Importers (/importers).”

FDA takes regulatory action based upon agency priorities, consistent with public health concerns and available resources.

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Can FDA inspect cosmetics manufacturers?

FDA can and does inspect cosmetic manufacturing facilities (/cosmetics/compliance-enforcement/inspection-cosmetics) to assure cosmetic product safety and determine whether cosmetics are adulterated or misbranded under the FD&C Act or FPLA.

Does FDA test cosmetics or recommend testing labs?

Although FD&C Act does not subject cosmetics to premarket approval by FDA, we do collect samples for examination and analysis as part of cosmetic facility inspections, import inspections, and follow-up to complaints of adverse events associated with their use. FDA may also conduct research on cosmetic products and ingredients to address safety concerns.

FDA does not function as a private testing laboratory, and in order to avoid even the perception of conflict of interest, we do not recommend private laboratories to consumers or manufacturers for sample analysis.

Do cosmetics firms need to register with FDA or get an FDA license to operate?

Under the law, manufacturers are not required to register their cosmetic establishments or file their product formulations with FDA, and no registration number is required to import cosmetics (/importers) into the United States.

However, we encourage cosmetic firms to participate in FDA's Voluntary Cosmetic Registration Program (VCRP) using the online registration system. Cosmetic manufacturers, distributors, and packers can file information on their products that are currently being marketed to consumers in the United States and register their manufacturing and/or packaging facility locations in the VCRP database. To learn more and access this program, see Voluntary Cosmetic Registration Program (VCRP) (/registration-program).

Related Resources

- Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?) (/cosmetics/laws-regulations/it-cosmetic-drug-or-both-or-it-soap)
- Key Legal Concepts: Interstate Commerce, Adulterated, and Misbranded (/cosmetics/laws-regulations/key-legal-concepts-interstate-commerce-adulterated-and-misbranded)
- Compliance and Regulation (/guidance-regulation)
- Labeling and Label Claims (/labeling-regulations)
- Exporting Cosmetics (/cosmetics/cosmetics-international-activities/cosmetics-exporters)
- Importing Cosmetics (/importers)

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Resources for You

- Federal Food, Drug, and Cosmetic Act (FD&C Act) (/federal-food-drug-and-cosmetic-act-fdc-act)
- FDA Recall Policy for Cosmetics (/cosmetics/recalls-alerts/fda-recall-policy-cosmetics)
- Inspection of Cosmetics: An Overview (/cosmetics/compliance-enforcement/inspection-cosmetics)